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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,167	07/03/2003	Marcus Pfister	32860-000579/US	4163

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EXAMINER	
TUCKER, WESLEY J	

ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,167	PFISTER, MARCUS	
	Examiner	Art Unit	
	WESLEY TUCKER	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-3-03, 4-30-04, 7-23-04 and 2-24-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 6-30 and 32-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,231,074 to Raunig.

With regard to claim 1, Raunig discloses ***an in vivo small animal image analysis process for automatic evaluation of at least one of two-dimensional and three-dimensional images of small animals, the images including at least one of one-dimensional, two-dimensional and three-dimensional image data*** (column 4, lines 37-45 and 58-63, Raunig discloses imaging small animals in situ in order to examine and analyze internal 2D and 3D images of animal), ***the process comprising:***

a) preparing the small animal (column 4, lines 37-45, Raunig discloses imaging a small animal with ultrasound imager, this will inherently require preparing the small animal or subject even if it is simply placing the animal in the path of the imager);

b) recording at least one of two-dimensional and three-dimensional images of the small animal via an imaging examination device (column 8, lines 4-21 and column 9, lines 63-67, Raunig discloses imaging tissue and recording both pixels or 2D image data as well as voxels or 3D data);

c) reading the at least one of two-dimensional and three-dimensional image data for the small animal (column 10, lines 3-13, Raunig discloses that the image data is read by a processor which computes useful statistics for the image data);

d) segmenting the image data, based upon image data characteristics, into segments, wherein the image data characteristics represent areas of interest for the small animal;

e) formatting cohesive areas by associating the segments on the basis of association criteria, wherein the cohesive areas are filtered by masking out remaining image data not associated with the cohesive areas (column 10, lines 14-25 and column 11, lines 1-8 and 51-67, Raunig discloses examining a tumor in a mouse by finding the outline of the tumor using pixel intensity values. The inside of the tumor is then examined further by grouping areas that are alike in characteristic. Therefore Raunig discloses formatting cohesive areas by finding the outline of the tumor and examining the area within the tumor effectively masking out the surrounding image area represented by area (1) in Fig. 7. Figs. 12A and 12 B illustrate a mask used to highlight a specific region of the image effectively masking out the surrounding region);

f) filtering the cohesive areas, when appropriate, and analyzing the cohesive areas based upon analysis criteria (column 22, lines 46-59, Raunig

discloses filtering the image to highlight and group portions within the region of interest. The areas are grouped by analysis of the image data);

g) storing at least one of the analyzed area data and segment data in a data memory; and h) repeating steps a) to g) for the same small animal at time intervals (column 3, lines 53-56 and column 4, lines 52-64, Raunig teaches that the purpose of using ultrasound imaging in a non-invasive manner is to examining the image of the tumor or region of interest over time through repeated comparisons which would inherently involve storing the image and repeating the steps of capturing, processing and storing new images fro comparison and study).

With regard to claim 2, Raunig discloses ***the image analysis process as claimed in claim 1, further comprising:***

i) quantifying at least one of the analyzed area data and segment data (column 5, lines 30-41, Raunig discloses classifying the region of interest or tumor in to quantities of necrotic or viable tissue);

j) comparing at least one of the quantified area data and segment data with at least one of stored area data and segment data from at least one previous analysis process (column 21, lines 16-22, Raunig teaches that the amount of necrotic and viable tissue is monitored by comparing the changes made in each quantity over an on-going treatment of the tumor or region of interest).

k) at least one of measuring and detecting a change in at least one of the segments and the cohesive areas (column 21, lines 16-22, Measuring and detecting

the a change is the objective in comparing the quantities in an on-going treatment or monitoring period); and

l) storing results in a databank (column 21, lines 16-22, column 3, lines 53-56 and column 4, lines 52-64, Storing the results from one change detection to the next is inherent to performing an kind of useful biological monitored study)

With regard to claim 3, Raunig discloses ***the image analysis process as claimed in claim 1, wherein the segmenting of the image data is carried out based upon the watershed algorithm, by at least one of region growing and conversion to binary form*** (column 23, lines 11-35, Raunig discloses converting the image regions to binary assigning 1 to necrotic and 0 to viable regions).

With regard to claim 4, Raunig discloses ***the image analysis process as claimed in claim 1, wherein the image data, before carrying out the step a), is determined by at least one of optical fluorescence, magnetic resonance, computer tomography and nuclear medical processes*** (column 4, lines 50-65, Raunig disclose the images are ultrasound).

With regard to claim 6, Raunig discloses ***the image analysis process as claimed in claim 1, wherein at least one of a centroid, a size, a mass and at least one substance concentration, at least one of obtained from the encoding of the image data and calculated from the image data, is used as the analysis criterion***

for analysis of the cohesive areas (column 5, lines 1-10, Raunig discloses calculating a centroid in grouping the different portions of the image).

With regard to claim 7, Raunig discloses ***the image analysis process as claimed in claim 1, wherein the measured changes in at least one of the segments and in the cohesive areas are stored as a dynamic sequence observation of at least one of a tumor and some other debilitation*** (column 11, lines 52-67, Raunig discloses that a tumor region is determined and processed. Raunig also teaches that the purpose of using ultrasound imaging in a non-invasive manner is to examining the image of the tumor or region of interest over time through repeated comparisons which would inherently involve storing the image and repeating the steps of capturing, processing and storing new images for comparison and study column 3, lines 53-56 and column 4, lines 52-64).

With regard to claim 8, Raunig discloses ***the image analysis process as claimed in claim 1, wherein the process steps a) to h) are carried out and displayed automatically on the basis of a predetermined workflow*** (column 5, lines 30-41, Raunig teaches that the operation is performed automatically in a specific order of steps by a processor and with a display).

With regard to claim 9, the discussion of claim 1 applies. Raunig discloses an apparatus fro performing the steps discussed with regard to claim 1. Raunig also

discloses the means for the performing the operation (column 5, lines 30-41). Raunig discloses an imager for imaging the recording the image and reading the image data as well as a processor for segmenting, forming and filtering regions of interest and a memory to store it all.

With regard to claim 10, the discussions of claim 1 and 2 apply.

With regard to claim 11, the discussion of claim 7 applies. The means for are the processor, memory and display devices discussed.

With regard to claims 12-16, the image data characteristics, association criteria, and analysis criteria are all interpreted to be predetermined. Raunig discloses determining different image property characteristics that must inherently be known in advance in order to automatically analyze and segment the image into regions of interest. See for example column 10, lines 3-25. the processor must be programmed with predetermined characteristics in order to perform the functions discussed ion claim 1.

With regard to claim 17, the discussion of claim 3 applies.

With regard to claim 18, Raunig discloses ***the image analysis process as claimed in claim 1, wherein the measured changes are displayed*** (Figs. 7-16B and

column 3, lines 53-56 and column 4, lines 52-64, Raunig teaches that the purpose of using ultrasound imaging in a non-invasive manner is to examining the image of the tumor or region of interest over time through repeated comparisons which would inherently involve storing the image and repeating the steps of capturing, processing and storing new images fro comparison and study. Raunig displays changes in a collection of images being used for comparison).

With regard to claim 19, the discussions of claim 1 and 2 apply. Raunig displays the changes monitored as discussed with regard to claims 1 and 2 (Figs. 7-16B).

With regard to claims 20-24, the discussions of claims 12-16 apply.

With regard to claim 25, the discussion of claim 1 applies. Claim 25 is a much broader version of claim 1.

With regard to claim 26, the discussion of claim 1 applies.

With regard to claim 27, the discussion of claim 1 applies.

With regard to claim 28, the discussion of claim 2 applies.

With regard to claim 29, the discussion of claim 3 applies.

With regard to claim 30, the discussion of claim 4 applies.

With regard to claim 32, the discussion of claim 1 applies.

With regard to claim 33, the discussions of claim 1, claim 9 and claim 25 apply. Raunig disclose the steps of claim 33 as discussed with regard to claim 1. Raunig also discloses an apparatus with means for as discussed with regard to claim 9.

With regard to claim 34, the discussion of claim 1 applies.

With regard to claim 35, the discussion of claim 2 applies. The means for is the processor discussed with regard to claim 9.

With regard to claim 36, the discussion of claim 3 applies.

With regard to claim 37, the discussion of claim 4 applies.

With regard to claim 38, the discussion of claim 1 applies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 5 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U.S. Patents 7,231,074 to Raunig and 6,842,638 to Suri et al.

With regard to claim 5, Raunig discloses the image analysis process as claimed in claim 1, but does not explicitly disclose ***wherein run length encoding is used as the association criterion for the associating of the segments in order to form cohesive areas, and wherein the cohesive areas are then post-processed.*** Run length encoding is a well known and commonly used technique in the art used for compression of images that have highly redundant image area regions. Suri teaches the use of a run length encoder to compress medical imagery after it has been converted into a binary image yielding only black and white values in the image (column 15, lines 40-67). Raunig's images of segmented tumors with mostly uniform areas outside of the region of interest or tumor for example would be ideal images to use with run length encoding. Highly uniform area around the tumor or region of interest such as

shown in Fig. 13B could be highly compressed thereby decreasing total image data to be stored and/or processed. Therefore it would have been obvious to one of ordinary skill in the art to use run length encoding as taught by Suri in the images of Raunig which consist of large highly redundant sections in order to compress the image thereby reducing the amount of data to store or process.

With regard to claim 31, the discussion of claim 5 applies.

Contact Information

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WESLEY TUCKER whose telephone number is (571)272-7427. The examiner can normally be reached on 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matt Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wes Tucker/
Examiner, Art Unit 2624